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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,027	06/29/2001	Olaf Iscle	8610	7458

27752 7590 07/20/2004

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EXAMINER
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CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/895,027	ISELE ET AL.
	Examiner Lakshmi S Channavajjala	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 01 March 2004.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-21 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

Claims 1-20 are previously presented. New claim 21 has been added. Claims 1-21 are pending.

The following rejection of record has been maintained:

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/64502 (hereafter WO).

Instant claims are directed to an article such as a diaper or a sponge, comprising a porous substrate having a contacting surface and an opposing surface, wherein the contacting surface is disposed with a beneficial agent and a means for minimizing migration of the beneficial agent into the porous substrate, whereby the ratio of the amount of beneficial component present in the top third portion of the substrate is about 2.2 times the amount of the beneficial agent present in the bottom 2/3 portion of the substrate. Dependents claims further define beneficial agents, disposing the beneficial agent in layers and method of top-biasing a composition on a porous substrate. Independent claim 9 recites a first layer of 5% to 95% of beneficial component on the contacting surface followed by a depositing a second layer. Independent claim 16 recites a method of top-biasing article by applying a first layer of relatively hydrophilic component followed by applying a relatively hydrophobic component allowing the first and second layers to cool without formation of an emulsion.

WO teaches an absorbent article having a liquid impermeable outer surface, a middle absorbent portion and a top liquid permeable bodyside liner facing the wearer (see figure 2 of WO). WO teaches that the bodyside liner may be made of woven or nonwoven materials, less hydrophilic to be dry, porous (page 12, lines 15-32). The bodyside liner includes a lotion formulation on the outer bodyfacing surface and is comprises wax, emollient and a viscosity

enhancer, that acts as a lubricant to reduce the abrasion of skin caused by liner and also transfers to the skin to provide improved skin health (abstract, page 13, lines 15-22) including fatty alcohols, lanolin or lanolin derivatives, petroleum based oils (page 13, lines 22-35), waxes for immobilizing the emollient and reduce its tendency to migrate (page 14), viscosity enhancers such as talc, silica, cellulose and modified cellulose derivatives and other skin treating compounds such as glycerin, zinc oxide, etc (page 15 and 16).

WO does not teach the claimed thickness of the beneficial components on the porous substrate i.e., 2.2 times more in the top third portion of the porous substrate than the bottom 2/3 portions. Further, WO teaches the lotion can be applied to the bodyside liner at 0.05-100 mg/sq. cm. Accordingly, it would have been within the scope of a skilled artisan to optimize the amounts of lotion applied on the absorbent applied on the article. The expected result would be a minimum migration of the solidified components applied to the bodyside line. A careful review of the instant specification also reveals that the same end result i.e., minimizing the migration of lotion is achieved by the applicants by incorporating viscosity enhancing agents (page 18) and hydrophobic agents such as wax, both of which are taught by WO. Further, WO states that a z-direction migration loss test shows that the migration of the lotion on the absorbent article is very low. With respect to the claims 9 and 16, WO does not explicitly teach layers of beneficial component or disposing a first hydrophilic layer followed by a hydrophobic layer. However, WO suggests limiting the lotion to restricted areas of the article such that migration to the interior or lateral migration of the absorbent body is not observed. Further, WO teaches applying the lotions to discreet areas as stripes as full length or a portion of the article and further in an add-on level, including the claimed steps of applying the component and solidifying (page 19). WO also

teaches deposition of wax, emollients and other viscosity enhancers such as celluloses, silica, petrolatum, aloe etc., all of which read on instant hydrophilic components, along with emollients and wax (hydrophobic) in the lotion formulation. WO suggests that the lotion formulation be applied to the entire body face or may be applied selectively to particular sections, so as to provide greater lubricity to such sections and can be applied in stripes (page 18, lines 26-33) and suggests adding the lotion to about 25% of the body facing surface of the bodyside liner. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to apply the lotion composition in a desired thickness or amounts with an expectation to exhibit minimum migration because WO suggests that the wax and viscosity enhancer containing lotion solidifies at the site of deposition due to the high melting agents and therefore do not migrate from their position (paragraph bridging pages 2-3). Further, adding the beneficial agents, hydrophobic or hydrophilic or both, in discreet patterns such as layers or stripes etc., and allowing the component to result in a proper composition, such emulsion formation or suspension or solution without affecting the optimum migration of the beneficial components would have been within the scope of a skilled artisan.

**New claim 21 has also been rejected over WO, for the reasons explained above.**

*Response to Arguments*

Applicant's arguments filed 3-1-04 have been fully considered but they are not persuasive.

Applicants argue that WO fails to teach or suggest at least two of the claimed limitations, namely, "beneficial component comprises at least a first and second layer" and "the claimed ratio

of 2.2" with respect to the thickness of the beneficial component. With respect to the argument that the minimum migration in WO is no more than 55%, applicants attention is directed to page 17 of WO, where it is clearly suggested that preferably the migration loss is no more than 55%, preferably no greater than 40%, more desirably no more than 35%. Thus, it is clear that both instant invention and WO desire the same result.

With respect to applicants' argument regarding the layers of beneficial component, instant claim 1 only states first and second layer, but does not require that the two layers be different. Therefore, if the both layers are to contain the same beneficial component, the process of layering the beneficial component only results in mixing up of the components and the layers do not remain distinct. Moreover, instant specification states (page 16) that the hydrophilicity and hydrophobicity of the first and second layers is not critical. Further, applicants have not shown any unexpected results with the beneficial component being in the form of layers as opposed to being applied as a single composition. Accordingly, incorporating the beneficial component on the article as a single (layer) component or as different layers by routine optimization would be within the ambit of a skilled artisan. Applicants argue that WO fails to teach the use of article for an inanimate surface. However, claim 2 recites the limitation in an intended use format, which carries no patentable distinction. Applicants argue that WO fails to teach hydrophobic and hydrophilic layers as in instant claim 5. However, as explained above, applicants themselves state that the relative hydrophilicity or relative hydrophobicity is not critical. Accordingly, if the two layers have same hydrophobicity or hydrophilicity to each other, the resulting beneficial component applied on the substrate would be the same as that of the WO.

Applicants argue that the office failed to show that the limitations of claim 8, i.e., inanimate articles. However, once again the claim recites an intended use. Moreover, “bandages” are usually employed for animate use and WO teaches the article for skin application. WO teaches emollients and viscosity enhancers, the latter group comprising polymers such as cellulose, which are also hydrophilic. Further, it has been admitted that the “relative” hydrophilicity or hydrophobicity is not critical and accordingly, choosing the desired beneficial component so as achieve the desired z-directional migration would have been within the scope of a skilled artisan. With respect to the new claim 21, as explained above, choosing the beneficial agents such that the migration of the beneficial component from the substrate is minimized would have been within the scope of a skilled artisan.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

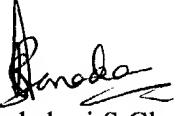
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1615

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
July 15, 2004

  
Gollamudi S. Kishore, PhD  
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Group 1600  
*Acting for TIC Page*